Form LHRHa-W: Worksheet for Designing Individual Field Trials Under LHRHa INAD 8061

INSTRUCTIONS

1. Investigator must fill out Form LHRHa-W for each trial conducted under this INAD **before** actual use of Luteinizing Hormone-Releasing Hormone analog. The Investigator is responsible that Form LHRHa-W is completed accurately.
2. Investigator should keep the original on file, and fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the AADAP Officefor assignment of the Study Number.
4. The AADAP Office will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
5. **Note:** Both Investigator and Study Monitor should sign and date Form LHRHa-W.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

		Fish species to be treated					
Average fish size (in)					Average fish weight (gm)		
Number of treated males					Number of treated females		
Number of control males					Number of control females		
Anticipated date treatment will be initiated					Estimated total amount of drug for proposed treatments (mg)		
Intended LHRHa dosage (ug/kg)		Female		Male	Method of administration		**Injection**
Number of injections		Female		Male	Injection interval (hrs or days)		
Drug manufacturer	**Western Chemical, Inc.**				Drug lot number		

STUDY DESIGN: Describe in detail the purpose of the clinical trial. For example you might compare dosage, or treated fish compared to untreated fish. Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

_____ Estimated time (days, months) from last treatment day to first possible harvest for human consumption

☐ Fish treated via injection will be maintained in culture facilities or captivity for at least 14 days following treatment before they are released or allowed to enter the food chain. Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section XV of the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

☐ Investigator should initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for Luteinizing Hormone-Releasing Hormone analog and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

FORM LHRHa-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form LHRHa-1 **immediately** upon receipt of LHRHa.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO.
4. **Note:** Both Investigator and Study Monitor should sign and date Form LHRHa-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act. The following information is submitted in triplicate:

Name of Drug	**LHRHa**	INAD Number	**8061**
Proposed Use of Drug	To induce gamete maturation in a variety of fish species.		
Date of CVM Authorization Letter	March 29, 2010		
Date of Drug Receipt		**Amount of Drug**	
Drug Lot Number		**Study Worksheet Number**	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study (yes/no)		Non-pivotal Study (yes/no)	
Approximate Number of Treated Animals		**Approximate Number of Control Animals**	
Number of Animals Used Previously[1]			
Study Protocol Number	8061		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	100 ug/Kg body weight		
Methods(s) of Administration	Injection or pellet implant		
Withdrawal Period	14 days for injection; No release of fish treated with pellet implant.		

[1] **To be filled out by the NIO**

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Date Reviewed: _____ **Sponsor:** _____

Form LHRHa – 2: Chemical Use Log for Clinical Field Trials Using Luteinizing Hormone- Releasing Hormone Analog Under INAD #8061

INSTRUCTIONS

1. Investigator should initiate a new form LHRHa-2 **immediately** upon receipt of each shipment of Luteinizing Hormone-Releasing Hormone analog.
2. Form LHRHa-2 should be updated whenever drug is used, transferred, or discarded.
3. Investigator should save all copies of this form until the end of the calendar year, at which time they should maintain all originals on file and send one copy of the completed form(s) to their Study Monitor. Within 10 days of receipt, the Study Monitor will ensure accuracy and send a copy to the AADAP Office for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form LHRHa-2.

Qty of LHRHa from previous page (mg) _____ Facility _____ Reporting individual _____

Date	Amount of new LHRHa received (mg)	Lot number of LHRHa received	Study Number	Amount of LHRHa used in treatment (mg)	LHRHa transferred (mg)	LHRHa discarded (mg)	LHRHa remaining on hand (mg)	Inventory by (Initials)
			xxxxxx	xx	xx	xx		
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Form LHRHa – 3: Results Report Form For Use of Luteinizing Hormone-Releasing Hormone Analog Under INAD 8061

INSTRUCTIONS

1. Investigator must fill out Form LHRHa-3 no later than 10 days after completion of the study period. Study Number must be recorded on all pages of Form LHRHa-3. Attach lab reports and other information.
2. If Luteinizing Hormone-Releasing Hormone analog was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 3 and fill out only the "Negative Report" section.
3. Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form LHRHa-3.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Drug lot number		Total amount drug used (mg)	
Fish species treated		Water temperature (°F)	
Drug dosage male (ug/kg body wt)		Drug dosage female (ug/kg body wt)	
Average fish weight (gm)		Average fish length (in)	
Number of treated males		Number of treated females	
Number of control males		Number of control females	
Treatment dates			
Injection Type (i.e. IM or IP)		Injection interval (hrs or days)	
Number of injections/males		Number of injections/females	
Spawning/evaluation interval (time from treatment until spawning)		Spawning/evaluation date	

Hormone Results Record - Version 4

INSTRUCTIONS

1. Green females are those fish that have not ovulated or released their eggs, green males are those fish that are not actively spermiating.
2. Motility Score based on a scale of 0 - 4 (see Study Protocol Section VI).
3. Use additional copies of this form for additional treatment days.

Be sure the facility name is written here:

		TREATED FISH - Females						CONTROL FISH - Females					
Date Treated	Date Evaluated	# of Fish	Number Ripe	Number Green	% Ripe	% Eye-Up	% Hatch	Number of Fish	Number Ripe	Number Green	% Ripe	% Eye-up	% Hatch

		TREATED FISH - Males						CONTROL FISH - Males					
Date Treated	Date Evaluated	# of Fish	Number Ripe	Number Green	% Ripe	Milt/ fish (mL)	Motility Score	# of Fish	Number Ripe	Number Green	% Ripe	Milt/ fish (mL)	Motility Score

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that

may have impacted treatment results? Were there any deviations from the Study Protocol? Attach pathology reports; Both Pre-and Post-Treatment.

Toxicity observations: Report any apparent drug toxicity including a description of unusual fish behavior.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period : _____ **no withdrawal period** _____ **14 days** _____ **no release**

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). _____

☐ **NEGATIVE REPORT** Luteinizing Hormone-Releasing Hormone Analog was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____